

Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

|       |   |    |   |
|-------|---|----|---|
| Sheet | 1 | of | 4 |
|-------|---|----|---|

**Complete if Known**

|                        |                 |
|------------------------|-----------------|
| Application Number     | 10/591,371      |
| Filing Date            | 09/01/2006      |
| First Named Inventor   | RUSSWURM        |
| Art Unit               | Unassigned 1634 |
| Examiner Name          | Unassigned      |
| Attorney Docket Number | 3535-022        |

## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

| FOREIGN PATENT DOCUMENTS |                       |   |                  |   |   |                |
|--------------------------|-----------------------|---|------------------|---|---|----------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T <sup>9</sup> |
|                          |                       | Country Code <sup>3</sup> *Number <sup>4</sup> *Kind Code <sup>5</sup> (if known) | MM-DD-YYYY       |   |   |                |
|                          |                       | EP 1 270 740 A1   | 01-02-2003       | SIRS-LAB GMBH                                   |   |                |
|                          |                       | WO 2004/087949 A2   | 10-14-2004       | SIRS-LAB GMBH                                   |   |                |
|                          |                       | WO 2004/031412 A2   | 04-15-2004       | ONCOTHERAPY SCIENCE                             |   |                |
|                          |                       | WO 03/002763 A1   | 01-09-2003       | SIRS-LAB GMBH                                   |   |                |
|                          |                       | WO 2004/067778 A2   | 08-12-2004       | UNIV. OF SOUTH FLORIDA                          |   |                |
|                          |                       | WO 99/40434   | 08-12-1999       | INVITROGEN                                      |   |                |

|                       |                    |                    |            |
|-----------------------|--------------------|--------------------|------------|
| Examiner<br>Signature | /Stephen Kapushoc/ | Date<br>Considered | 02/25/2010 |
|-----------------------|--------------------|--------------------|------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

|   |      |                          |                     |
|---|------|--------------------------|---------------------|
| Substitute for form 1449/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |      | <b>Complete if Known</b> |                     |
|   |      | Application Number       | 10/591,371          |
|   |      | Filing Date              | 09/01/2006          |
|   |      | First Named Inventor     | RUSSWURM            |
|   |      | Art Unit                 | Unassigned 1634     |
|   |      | Examiner Name            | Unassigned Kapushoc |
| Sheet 2   | of 4 | Attorney Docket Number   | 3535-022            |

| NON PATENT LITERATURE DOCUMENTS |                       |   |                |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                                 |                       | BARRIERE, et al., "An overview of mortality risk prediction in sepsis", Crit Care Med, 23:2, 376-393 (1995).  |                |
|                                 |                       | BOTWELL, DAVID, D. L., "Options available - from start to finish - for obtaining expression data by microarray", Nature Genetics Supplement, 21: 25-32 (1999).  |                |
|                                 |                       | CHINNAIYAN, et al., "Molecular Signatures of Sepsis, Multiorgan Gene Expression Profiles of Systemic Inflammation", American Journal of Pathology, 159:4, 1199-1209 (2001).   |                |
|                                 |                       | COBB, et al., "Sepsis gene expression profiling; Murine splenic compared with hepatic responses...", Crit Care Med 30:12, 2711-2 (2002).  |                |
|                                 |                       | "Microarray expression profiling: Towards an application in sepsis diagnostics", URL: <a href="http://www.sirs-lab.de/content/de/pdf/kompetenzen/deigner.pdf">http://www.sirs-lab.de/content/de/pdf/kompetenzen/deigner.pdf</a> , (2004).                       |                |
|                                 |                       | MIRA, et al., "Association of TNF2, a TNF- Promoter Polymorphism, with Septic Shock Susceptibility and Mortality", JAMA 208:6, 561-8 (1999).  |                |
|                                 |                       | PATHAN, et al., "The Complexity of the Inflammatory Response to Meningococcal Sepsis Revealed by Gene Expression...", Crit Care Med, 30:12 Suppl. (2003).   |                |
|                                 |                       | PRUCHA, et al., "Expression Profiling: Toward an Application in Sepsis Diagnostics", Shock, 22:1 29-33 (2004).  |                |
|                                 |                       | SCHLAG, G., et al., "The cell in shock: the origin of multiple organ failure", Resuscitation 21:2-3, 137-80 (1991).   |                |
|                                 |                       | YU, et al., "Differential gene expression in gram-negative and gram-positive sepsis", Am J Respir Crit Care Med 169:10, 1135-43 (2004).   |                |

|                    |                    |                 |            |
|--------------------|--------------------|-----------------|------------|
| Examiner Signature | /Stephen Kapushoc/ | Date Considered | 02/25/2010 |
|--------------------|--------------------|-----------------|------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

|   |      |                          |                     |
|---|------|--------------------------|---------------------|
| Substitute for form 1449/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |      | <b>Complete if Known</b> |                     |
|   |      | Application Number       | 10/591,371          |
|   |      | Filing Date              | 09/01/2006          |
|   |      | First Named Inventor     | RUSSWURM            |
|   |      | Art Unit                 | Unassigned 1634     |
|   |      | Examiner Name            | Unassigned Kapushoc |
| Sheet 3   | of 4 | Attorney Docket Number   | 3535-022            |

| NON PATENT LITERATURE DOCUMENTS |                       |  |                |
|---------------------------------|-----------------------|--|----------------|
| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                                 |                       | HELLER, et al., "Discovery and analysis of inflammatory disease-related genes using cDNA microarrays", Proc. Natl. Acad. Sci USA, 94: 2150-55 (1997).  |                |
|                                 |                       | MEMBERS OF THE ACCP/SCCM... "...Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis", Crit Care Med, 20:6 864-874 (1992).  |                |
|                                 |                       | OBERHOFFER, et al., "Discriminative power of inflammatory markers for prediction of tumor necrosis...", Intensive Care Med, 26:S170-S174 (2000).   |                |
|                                 |                       | ROWE, et al., "An Array of Immunosensor for Simultaneous Detection of Clinical Analysis", Anal. Chem. 71:433-39 (1999).  |                |
|                                 |                       | WEIGAND, et al., "Gene Expression Pattern in Human Monocytes as a Surrogate Marker for Systemic Inflammatory Response Syndrome (SIRS)", Molecular Medicine, 5:192-202 (1999).  |                |
|                                 |                       | WOZNEY, et al., "Homo sapiens (clone KT2) bone morphogenetic protein-1 (BMP-1) mRNA and alternatively spliced...", Database accession no. L35279, Eur. Mol Bio Lab (1995).   |                |
|                                 |                       | DATABASE NETAFX,<br>"www.affymetrix.com/analysis/netaffx/probematch/probe_match.affx?netaffx=netaffx4_annot" (2006).   |                |
|                                 |                       | GALDERISI, et al., "Antisense Oligonucleotides as Therapeutic Agents", Journal of Cellular Physiology 181:251-257 (1999).  |                |
|                                 |                       | JANSEN, et al., "Antisense therapy for cancer - the time of truth", The Lancet Oncology, 3:672-683 (2002).   |                |
|                                 |                       | LIU, et al., "Gene expression profiles in human nasal polyp tissues studied by means of DNA microarray", J Allergy Clin Immunol, 114:4 783-790 (2004).   |                |

|                    |                    |                 |            |
|--------------------|--------------------|-----------------|------------|
| Examiner Signature | /Stephen Kapushoc/ | Date Considered | 02/25/2010 |
|--------------------|--------------------|-----------------|------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

|  |      |                          |                                |
|--|------|--------------------------|--------------------------------|
| Substitution for form 1449/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(Use as many sheets as necessary)</i> |      | <b>Complete if Known</b> |                                |
|  |      | Application Number       | 10/591,371                     |
|  |      | Filing Date              | 09/01/2006                     |
|  |      | First Named Inventor     | RUSSWURM                       |
|  |      | Art Unit                 | Unassigned xxxxxxxxxx 1634     |
|  |      | Examiner Name            | Unassigned xxxxxxxxxx Kapushoc |
| Sheet 4  | of 4 | Attorney Docket Number   | 3535-022                       |

| NON PATENT LITERATURE DOCUMENTS |                       |   |                |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                                 |                       | RAY, et al., "Peptide nucleic acid (PNA): its medical and biotechnical applications and promise for the future", The FASEB Journal, 14:1041-1060 (2000).  |                |
|                                 |                       | RIESEWIJK, et al., "Gene expression profiling of human endometrial receptivity on days LH+2 versus LH+7 by microarray technology", Mol Human Reprod, 9:5 253-264 (2003).  |                |
|                                 |                       | TSUKAHARA, et al., "Gene Expression in Human Neutrophils During Activation and Priming by Bacterial Lipopolysaccharide", Journal of Cellular Biochemistry, 89:848-861 (2003).   |                |
|                                 |                       |   |                |
|                                 |                       |   |                |
|                                 |                       |   |                |
|                                 |                       |   |                |
|                                 |                       |   |                |
|                                 |                       |   |                |
|                                 |                       |   |                |
|                                 |                       |   |                |

|                    |                    |                 |            |
|--------------------|--------------------|-----------------|------------|
| Examiner Signature | /Stephen Kapushoc/ | Date Considered | 02/25/2010 |
|--------------------|--------------------|-----------------|------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /STK/